ALASKA MEDICAID
PHARMACY AND THERAPEUTICS COMMITTEE

Location of Meeting
Frontier Building, 3601 C Street, Room 890/896

FINAL MINUTES OF MEETING
April 15, 2011
8:00 a.m.

Committee Members Present:
Dharna Begich, Pharm.D.
Marvin Bergeson, MD
Robert H. Carlson, MD
Jeffrey G. Demain, MD, Co-Chair
Mary-Beth Gardner, ANP
Vincent Greear, R.Ph. (telephonic)
Daniel P. Kiley, DDS MPH
Diane Liljegren, MD (telephonic)
William McCormick, Pharm.D. (telephonic)
Paul Michaud, Pharm.D.
John Pappenheim, MD
Jill Reid, R.Ph. (telephonic)
Trish White, R.Ph. (telephonic)

Committee Members Absent:
Amber Briggs, Pharm.D.
Richard Brodskey, MD, Chair
Claudia Phillips, MD

Others Present:
David Campana, R.Ph.
Julie A. Pritchard, Pharm.D.
Chad Hope, Pharm.D.
Flora Solomon
Christine Arnold, Kron Associates

1. Call to Order – Co-Chair

Dr. Demain called the meeting to order at 8:00 a.m. Mary-Beth Gardner, a new member and nurse practitioner from Fairbanks, was introduced. John Riley, a physician's assistant from UAA, will be joining the committee at the next meeting. Ms. Stables and Dr. Macjewski, who were rotated off the committee, were thanked for their work.

2. Roll Call

A quorum was present.

3. Public Comments

There were no public comments.

4. Review of Ophthalmic Macrolides (Red Category)

There were no public testimonies.

Dr. Pritchard gave the Magellen presentation on Ophthalmic Macrolides, which are used for bacterial conjunctivitis or superficial ocular infections of the conjunctiva or cornea. The mechanism of action is to inhibit protein synthesis. Both have very low side effect profiles with itching, discomfort and transient burning being reported at low rates. Azithromycin appears to be more favorable as far as the side effect profile, but Erythromycin is the drug of choice for infants. The formulations and dosing of Azithromycin and Erythromycin were reviewed. In March, there were 132 claims: 92% for Erythromycin and 8% for Azasite. There was no previous discussion as this is a new class.

DR. BERGESON MOVED THE DRUGS IN THE CLASS WERE THERAPEUTIC EQUIVALENTS, WITH ERYTHROMYCIN OINTMENT BEING INCLUDED ON THE PDL. SECONDED BY DR. MICHAUD. THE MOTION PASSED UNANIMOUSLY.

5. Review of Self-Injectable Epinephrine (Red Category)

There were no public testimonies.

Dr. Pritchard gave the Magellen presentation on Self-Injectable Epinephrine, which is used in cases of anaphylaxis reaction. It exhibits action on both alpha and beta adrenergic receptors, thereby serving to alleviate hypotension, loss of intravascular fluid, and bronchospasm. Reported adverse reactions were reviewed. There are no absolute contraindications in the face of a life-threatening reaction. Infants, or those under 25 kilograms, should be given the pediatric dose. Doses are premeasured and the delivery devices were reviewed. In March, there were 116 claims: 85% for Epi-Pen, 12% for generic Epinephrine, and 3% to Twinject. There was no previous discussion as this is a new class. Epinephrine is now available as a generic. Dr. Eric Meier states that there should always be two doses available. A patient may be re-dosed within two to three minutes, if needed. Epinephrine must be an IM injection and injection is recommended in the thigh. The drugs are all similar even though the delivery devices differ. One advantage of the Epi-Pen is that the needle is covered for safety.

Dr. Demain, after noting that both the drugs and doses were the same, passed around three delivery devices and noted that the decision would really be about the technology rather than the drug. The three delivery devices were examined and Dr. Demain explained how they worked.

In response to several questions, Dr. Demain said none of the delivery devices were difficult to use, but many patients like the Epi-Pen since they are familiar with it. Whenever device is prescribed, the patient is taught its proper use, and often that choice is based on what their insurance plan covers. About 2 to 4 percent of the patients prescribed Epi-Pens actually have to use them. A survey conducted by Gail White, a school nurse, on how many school nurses had administered Epinephrine was discussed. There were 35 injections done over a three-year period, and more times when the nurses felt one should have been given. The number of fatalities when Epinephrine shots were delayed versus the lack of fatalities when the shots were given was discussed.

The committee discussed patient education on delivery devices that may be needed because of changes in the PDL. A pharmacist can teach a patient how to use a new delivery device and the grandfather clause can be utilized so patients can receive the delivery devices they currently use. Dr. Carlson pointed out that some remote areas did not have pharmacists. It was noted that the medically necessary clause could be utilized as well. Dr. Michaud suggesting including both a pediatric and adult dosage.

DR. BERGESON MOVED A CLASS EFFECT, TO INCLUDE BOTH A PEDIATRIC AND ADULT DOSAGE ON THE PDL. SECONDED BY DR. MICHAUD. THE MOTION PASSED WITH ONE OPPOSED.

Dr. Demain said information needed to be sent out to all pharmacies letting the pharmacists know that they will be responsible for teaching patients how to use new delivery devices should they be changed.

Dr. White expressed concern that there was no grandfather clause in the motion. The medically necessary clause is sometimes hard to use when a patient needs their medication immediately. Mr. Campana said the grandfather clause only applies to those medications where it is specifically mentioned in the motion. The committee further discussed the grandfather clause.

DR. WHITE MOVED TO GRANDFATHER ANY EPI A PATIENT IS CURRENTLY USING. SECONDED BY DR. CARLSON. THE MOTION PASSED UNANIMOUSLY.

6. Review of Antiviral - Influenza (Red Category)

There were no public testimonies.

Dr. Pritchard gave the Magellen presentation on Antiviral - Influenza. All available products should be administered as quickly as possible after onset of symptoms and not later than 48 hours after. Not all products are effective for all variations of influenza. The prescriber should be aware of susceptibility patterns when considering chemical treatment. Vaccinations should still be the primary form of prophylaxis. Relenza and Tamiflu are indicated for types A and B; whereas Amantadine and Rimantadine are only indicated for type A. Relenza does have age issues, as well as the cautionary statement to those patients with milk allergies. In March, there were 209 claims: 100% for Tamiflu. There were 29 claims for Amantadine, but it is unknown if that was for the flu or Parkinson's Disease. There was no previous discussion as this is a new class.

Dr. Hope did not feel the agents in this class were the same. Many of these agents are inferior when dealing with the influenza strains. Dr. Michaud said the CDC had dosing guidelines for Tamiflu for the pediatric population. You cannot use some of the other drugs in young children and they can have severe complications with the flu.

DR. BERGESON MOVED THE DRUGS IN THE CLASS WERE THERAPEUTIC ALTERNATIVES, PREFERENTIALLY INCLUDING TAMIFLU ON THE PDL. SECONDED BY DR. CARLSON. THE MOTION PASSED UNANIMOUSLY.

7. Re-Review of Ophthalmic Quinolones (Blue Category)

There were no public testimonies.

Dr. Pritchard gave the Magellen presentation on Ophthalmic Quinolones. All available products, except Levofloxacin 1.5%, are indicated for the treatment of bacterial conjunctivitis. Levofloxacin 1.5% is only indicated for treating corneal ulcers. Ofloxacin and Ciprofloxacin solution may also be used for corneal ulcers. Fluoroquinolones exert activity by inhibiting DNA gyrase, which is an enzyme needed for replication, transcription and repair of bacterial DNA. All products are available in solution

form. Ciprofloxacin also comes as an ointment. In March, there were 183 claims: 50% for Vigamox, 21% for Ofloxacin drops, 21% for Ciprofloxacin, 5% for Zymar, and the rest had less than 9 claims. At the last review, a motion for class effect passed unanimously. Significant changes include Gatifloxacin and Moxifloxacin appear to have better activity against gram positive and resistant organisms than other quinolones. Most products are dosed four or more times a day, except Moxifloxacin is dosed two to three times a day and Besifloxacin is dosed three times a day.

Dr. Liljegren suggested declaring a class effect, but preferring one of the agents with a decreased frequency of dosing, which increases compliance. Dr. Carlson suggested declaring a class effect and utilizing the medically necessary clause as necessary.

DR. CARLSON MOVED A CLASS EFFECT. SECONDED BY DR. BERGESON. THE MOTION PASSED UNANIMOUSLY.

8. Re-Review of Intranasal Antihistamines (Blue Category)

There were no public testimonies.

Dr. Pritchard gave the Magellen presentation on Intranasal Antihistamines. Intranasal Antihistamines have proved as effective or superior to oral 2nd generation products for relief of seasonal allergic rhinitis symptoms. Olopatadine is a selective H-1 receptor antagonist, but both products can cause CNS depression, possibly causing a decrease in alertness. All are dosed at one to two sprays in each nostril, twice daily. In March, there were 9 claims: 56% for Patanase, 33% for generic Azelastine, and 11% for Astepro. At the last review, a motion for class effect passed unanimously. Significant changes include Azelastine is available as a generic.

Dr. Demain felt the agents were interchangeable, although there may be more sedation with the Azelastine preparation.

DR. BERGESON MOVED A CLASS EFFECT. SECONDED BY DR. BEGICH. THE MOTION PASSED UNANIMOUSLY.

9. Re-review of Nasal Steroids (Blue Category)

There were no public testimonies.

Dr. Pritchard gave the Magellen presentation on Nasal Steroids. The 2008 guidelines list nasal corticosteroids as most effective products for treating allergic rhinitis. They are also used to treat symptoms of non-allergic rhinitis. Clinical trials show all are similar in efficacy, although there may be patient preference for spray or mist formulations. Differences between products are the number of sprays and frequency of dosing. In March, there were 672 claims: 58% for Nasonex, 15% for Fluticasone Propionate, 8% for Flunisolide, 6% for Nasacort AQ, 6% for Veramyst, 4% for Omnaris, 2% for Rhinocort Aqua, and less than 5 claims for the rest. At the last review, a motion for class effect, to include one aqueous preparation and one indicated for age 2 and above, passed unanimously. Significant changes include Flunisolide is only available generically now.

DR. BERGESON MOVED A CLASS EFFECT, TO INCLUDE ON AQUEOUS PREPARATION AND ONE INDICATED FOR AGE 2 AND ABOVE. SECONDED BY DR. LILJEGREN. THE MOTION PASSED UNANIMOUSLY.

10. Re-Review of Ophthalmic NSAIDS (Blue Category)

Dr. Dominick Marini: A representative of ISTA discussed Bromday. Bromday is a .09% ophthalmic solution indicated for the treatment of postoperative inflammation and the reduction of ocular pain in patients who have undergone cataract surgery. Bromday, which was approved in October 2010, is the first and only ophthalmic NSAID dosed once daily. Ophthalmic solution has been extensively studied in Japan and the United States. It has been shown to be safe and effective in the treatment of post cataract surgery. Several studies and their outcomes were reviewed. Dr. Marini explained the mechanism of action of Bromday. In conclusion, Bromday is the only topical ophthalmic NSAID approved for once daily dosing, beginning one day prior to cataract surgery and two weeks post-op. This provides the least amount of drops for a full course of therapy of 16 drops, and the lowest daily dose of BAK. Given the post cataract surgery regiment often contains more than one ophthalmic agent, separated by at least 5 to 15 minutes to avoid washout, this may be challenging for many patients and result in poor adherence to the prescribed regimen. A dosing regimen of one drop, once daily, of Bromday reduces the frequency of installations while maintaining efficacy and may provide improved compliance.

Dr. Pritchard gave the Magellen presentation on Ophthalmic NSAIDS. The main use of these products is to relieve inflammation and pain associated with ophthalmic surgery. Use for longer than 14 days increases risk of adverse corneal events. Transient burning, irritation, and corneal edema are the most commonly reported adverse effects. These products have no significant effect on intraocular pressure. After cataract surgery, Diclofenac and Nevanac have been associated with an elevation of pressure. Frequency and number of drops vary between agents, but all show similar efficacy. In March, there were 36 claims: 47% for Lotemax, 19% for Diclofenac, 11% for Nevanac, and the rest of the products were less than 10%. At the last review, a motion for class effect passed unanimously. Significant changes include Bromday replaced Zybrom. Bromvanac, Ketorolac and Nevanac should not be used while wearing contact lenses.

DR. MICHAUD MOVED A CLASS EFFECT. SECONDED BY DR. CARLSON. THE MOTION PASSED UNANIMOUSLY.

Dr. Demain reminded the committee that the medically necessary clause could always be utilized.

11. Re-review of Ophthalmic Anti-Allergy Agents (Blue Category)

Dr. Dominick Marini: A representative of ISTA discussed Bepreve. Bepreve is indicated for the treatment of itching associated with signs and symptoms of allergic conjunctivitis. It is a new molecule compared with what is currently on the formulary. Bepreve is a topically active, direct H-1 receptor antagonist and an inhibitor of the release of histamine from mass cells. With specificity to the H-1 receptor, there are no side effects like dry eye and dry mouth that the other products have. The mechanism of action was reviewed. It has a long track record of safety as it has been in Japan for more than 10 years with more than 1 billion systemic doses administered, and it was approved in the U.S. in September 2009. Several studies and their outcomes were reviewed. The dosage is one drop in the

effected eye, twice a day. It has been shown to be effective in reducing ocular itching associated with allergic conjunctivitis. It has a rapid onset of action, within 3 minutes, and a durable response, lasting 8 hours after dosing. It has demonstrated to be safe and comfortable. It is also indicated for patients 2 years and above. It also offers around the clock therapy, which reduces breakthrough itch that requires unnecessary prescription refills.

Dr. Pritchard gave the Magellen presentation on Ophthalmic Anti-Allergy Agents. These agents are used to treat symptoms of perennial and seasonal allergies. These products should not be used to treat contact lens irritation as they contain the preservative benzalkonium chloride. Contact lens may be reinserted 10 minutes after administration of drops. All products are in solution form and dosed as 1 drop, but the frequency of dosing varies among agents. In March, there were 117 claims: 47% for Patanol, 42% for Pataday, and the rest were less than 10%. At the last review, a motion for class effect passed unanimously. Significant changes include Azelastine is now available as a generic. A community prescriber submitted a letter requesting that Bepreve be included on the PDL.

Dr. Demain said all of the drugs work well. Bepreve, Patanol, and Pataday may be better tolerated by adults and children, as they are less irritating to the eye. The solution for Bepreve, at 10 milliliters, is almost twice the amount of comparable drugs, so a single bottle lasts longer. The difference between this class and mass cell stabilizers was reviewed.

DR. BERGESON MOVED A CLASS EFFECT. SECONDED BY DR. CARLSON. THE MOTION PASSED UNANIMOUSLY.

12. Re-review of Anti-Migraines (Blue Category)

There were no public testimonies.

Dr. Pritchard gave the Magellen presentation on Anti-Migraines, which come in a variety of forms. Triptan products include a warning regarding the possibility of serotonin syndrome when used in conjunction with SSRIs. Patients with other significant underlying cardiovascular diseases should not receive Sumatriptan/Naproxen (Treximet), nor should patients who have undergone coronary artery bypass graft surgery. REMS are required for these two products. The injectable agents tend to work within 10 minutes of administration, but others are found to be equally safe. In March, there were 257 claims: 31% for Maxalt MLT, 29% for Sumatriptan Tablets, 16% for Maxalt, and the rest of the products were all less than 10%. At the last review, a motion for class effect passed unanimously. Significant changes include Cambia and Alsuma came to the marketplace. Amerge is now available generically as Naratriptan.

After Dr. Liljegren suggested that an injectable formulation be included on the PDL for patients who wake up with migraines, Mr. Campana said the medically necessary clause could be used due to the low number of monthly claims.

DR. PAPPENHEIM MOVED A CLASS EFFECT. SECONDED BY DR. BERGESON. THE MOTION PASSED UNANIMOUSLY.

13. Re-review Anti-Emetics (Blue Category)

There were no public testimonies.

Dr. Pritchard gave the Magellen presentation on Anti-Emetics. Prevention of chemo or radiation therapy induced nausea and vomiting is the goal of these products. The three main classes of anti-emetics were reviewed. There can also be nausea and vomiting associated with motion sickness, which occurs when the signals received from the eyes do not match those received from the inner ear. 5-HT3 antagonists are the first line drugs to prevent the nausea and vomiting associated with chemotherapy or radiation therapy. Studies show no significant differences among products in this class. In March, there were 419 claims: 47% for Ondansetron HCL Tab Rapids, 45% for Ondansetron HCL Tablets, and the rest of the products were less than 10%. At the last review, a motion for class effect passed unanimously. Significant changes include Apromorphine with Ondansetron is contraindicated as it may cause severe hypotension and loss of consciousness.

In response to Dr. Demain, Dr. Pritchard said the committee was only considering the oral anti-emetics for chemo and radiation therapy induced nausea and vomiting.

The committee discussed whether Amend was included in this class. Mr. Campana said Amend had been included in the past.

DR. LILJEGREN MOVED THE DRUGS IN THE CLASS WERE THERAPEUTIC ALTERNATIVES. SECONDED BY DR. BERGESON. THE MOTION PASSED UNANIMOUSLY.

14. Re-review of Inhaled Steroids (Blue Category)

Kevin Byrne: A representative of GlaxoSmithKline discussed Advair. The REMS program was updated as part of the labeling change for Advair. All medications with a long-acting beta agonist (LABA) and an indication for asthma are required to implement a REMS program. The goal of the program is to inform healthcare provider and patients of the increased risk of asthma related death and serious outcomes with LABA containing medications, as well as their appropriate use for asthma. The REMS program for Advair will include the following. A medication guide will be dispensed with each prescription. A "Dear Healthcare Professional" letter, as well as a letter to medical societies, will be provided to inform them about the increased risk of asthma related death. In addition, new prescribing guidelines will be distributed. The initial mailing is currently underway and a second distribution will be done about six months following post-REMS approval, which occurred in January of this year. Printed and web-based safety information for healthcare providers will be posted on the GSK website. The information refers to the following. Advair should only be used in patients not adequately controlled on a long-term asthma controller such as an inhaled steroid or whose disease severity clearly warrants initiation with two maintenance medications. Once asthma control is achieved and maintained, patients should be assessed at regular intervals. Step down therapy, if possible without loss of asthma control, and maintain the patient on long-term asthma control medication such as an inhaled steroid. Advair should not be used in patients whose asthma is adequately controlled on lower, medium dosed inhaled steroids. Therefore, the availability of Advair, as well as Flovent, as therapeutic alternatives for patients with asthma will be important. Advair is currently approved patients 12 years

of age and older, as well as the MDI version. Advair provides a variety of dosage options, which were described, and allows patients to stay with the same medication and delivery system.

Dr. Pritchard gave the Magellen presentation on Inhaled Steroids. Inhaled steroids are the most effective option in treating persistent asthma according to the 2007 guidelines. Many patients will still require higher doses or adjunctive therapy with agents from another class. Most agents are dosed twice daily. Mometasone can be once daily and Triamcinolone (ph) can be used up to four times daily. Products containing Salmeterol or Formoterol should be used with caution in those patients on monoamine oxidase inhibitors, tricyclic antidepressants, or drugs known for QTc prolongation. In March, there were 1,056 claims. There were 549 for inhalers, 507 for combination products, and 88 for nebulized products. For the inhalers: 56% for Flovent HFA, 16% for Qvar, and the rest in the inhaled corticoid steroid single were less than 10%. For the combination products: 73% for Advair Diskus, 18% for Symbicort, and less than 10% for the others. For the nebulized corticosteroids: 54 claims for Budesonide and 35 for Pulmicort. At the last review, a motion to include one low to medium potency, one high potency, and Budesonide passed unanimously. Significant changes include Dulera is available for treatment of asthma in patients 12 and older. The combination products should be reserved for patients not adequately controlled on a long-term inhaled corticosteroid.

Mr. Campana noted that the vote would only be for inhaled corticosteroids. Combination products are placed on the PDL if the single agent entity is preferred and it is cost effective.

Dr. Demain pointed out that due to FDA rules, a combined agent must be included on the PDL. The committee discussed why Budesonide, which is a preferred agent, does not have a "Y" next to it on the PDL. Budesonide is the preferred agent for pregnant patients and younger patients. Dr. Pritchard did not know why the "Y" was missing from the PDL.

DR. BERGESON MOVED A CLASS EFFECT, TO INCLUDE ONE HIGH DOSE, ONE LOW TO MEDIUM DOSE, ONE COMBINED PRODUCT, AND NEBULIZED BUDESONIDE. SECONDED BY DR. KILEY. THE MOTION PASSED UNANIMOUSLY.

15. Re-review of Leukotriene Inhibitors (Blue Category)

There were no public testimonies.

Dr. Pritchard gave the Magellen presentation on Leukotriene Inhibitors. This class of medication is used as an add-on therapy in patients with mild persistent symptoms or aspirin sensitive asthma. They are also used in patients utilizing inhaled corticosteroids to reduce the steroid dose. Leukotriene-mediated effects include airway edema, smooth muscle contraction, mucous secretion, micro vascular permeability, and altered cellular activity associated with the inflammatory process. Accolate is to be dosed on an empty stomach, which is 30 minutes before a meal or 2 hours after. In March, there were 1,101 claims: 54% for Singular Tablet, 42% for Singular Chew Tabs, 3% for Singular Granules, and 3 claims for Zafirlukast and 1 claim for Accolate. At the last review, a motion for therapeutic alternatives, to prefer all forms of Singular, passed unanimously. Significant changes include Accolate is available generically. Patients on Montelukast may present with systemic eosinophilia, but the causality is not defined at this time.

Dr. Demain discussed Accolate (Zafirlukast). It is dosed twice daily and must be taken 30 minutes before a meal or 2 hours after a meal. If it is not used in that manner, there can be a 30 to 60% loss of bioavailability. It is not indicated for younger children. There have also been some concerns about the leukatry modifiers in regard to mood changes, suicidality, and aggressiveness in children.

DR. BEGICH MOVED THE DRUGS IN THE CLASS WERE THERAPEUTIC ALTERNATIVES, TO INCLUDE ALL FORMS OF SINGULAR. SECONDED BY DR. BERGESON. THE MOTION PASSED UNANIMOUSLY.

16. Re-review of Anti-Herpes Oral Medication (Blue Category)

There were no public testimonies.

Dr. Pritchard gave the Magellen presentation on Anti-Herpes Oral Medication. HSV infections are the leading cause of genital ulcerations in the United States. HSV-2 has been found to increase the risk of acquiring HIV. Oral antiviral therapy is preferred over topical. In fact, the use of topical products is to be discouraged according to the 2010 CDC STD recommendations. Anti-virals reduce the duration of viral shedding, new lesion formation, and reduces rash healing time. Renal failure resulting in death has been noted with all products, but they all have similar efficacy. In March, there were 343 claims: 51% for Valacyclovir, 27% for Acyclovir Tablet/Capsule, and less than 10% each for the rest of the products. At the last review, a motion for class effect passed unanimously. Significant changes include Valacyclovir should be discontinued if CNS side effects occur.

In response to Dr. Demain, Dr. Pritchard explained why topical formulations were discouraged. Topical formulations, which are a separate class, are used for oral ulcerations and not genital lesions.

DR. CARLSON MOVED A CLASS EFFECT, TO INCLUDE A SUSPENSION AND A CAPSULE/TABLET FORMULATION. SECONDED BY DR. BERGESON.

DR. MICHAUD OFFERED A FRIENDLY AMENDMENT TO INCLUDE AN ORAL SUSPENSION AND A CAPSULE/TABLET TO THE PDL. THE MAKER OF THE MOTION AND THE SECOND CONCURRED. THE MOTION PASSED UNANIMOUSLY.

17. Re-review Topical Antiviral Agents (Blue Category)

There were no public testimonies.

Dr. Pritchard gave the Magellen presentation on Antiviral Agents. These products are used for cold sores occurring from either an HSV-1 or 2 infection. Recurrences resulting from an HSV-2 are rare. About 80% of the adult population in the U.S. is infected. Abreva is the only FDA approved OTC medication and the mechanism of action is unknown. Systemic absorption from topical antivirals is low. Topical therapy should be started during the prodome period and used for acute outbreaks only. In March, there were 33 claims: 55% for Zovirax Ointment, 33% for Zovirax Cream, and 12% for Denavir. At the last review, a motion for class effect passed unanimously. Significant changes include Xerese, a combination product of Acyclovir and Hydrocortisone became available for treatment of cold sores for patients 12 year of age and older. It is applied five times a day for five days.

Dr. Hope noted that the guidelines discouraged the use of topical agents for the genital area, yet Zovirax ointment and cream are indicated for genital lesions. The committee discussed whether the use of topical agents for the genital area should be discouraged on the PDL. Dr. Bergeson noted that they were also used for oral lesions and should be not eliminated from the PDL. Mr. Campana suggested the committee determine whether these drugs would be preferred or non-preferred, and then the DUR Committee could decide whether a prior authorization was necessary for these agents. Dr. Hope requested that the data discouraging use of topical agents on genital areas be provided at the next meeting. It was decided the committee would vote on the class and then further discuss the agents used for genital use in September. The findings of the DUR Committee will be reported at the meeting following the September meeting.

DR. CARLSON MOVED A CLASS EFFECT. SECONDED BY DR. KILEY. THE MOTION PASSED UNANIMOUSLY.

18. Re-review of Hepatitis B - Oral (Blue Category)

There were no public testimonies.

Dr. Pritchard gave the Magellen presentation on Hepatitis B - Oral. All four products are indicated for use in patients with chronic hepatitis B, viral infection, prolonged antiviral therapy is needed for suppression of chronic hepatitis B. Epivir HBV can be used in those 2 years and older. Hepsera can be used in those 12 years and older. The others are used for those 16 years and older. The guidelines are expected to be updated in 2011, but the 2009 recommendation was to use Baraclude. In March, there were 8 claims: 5 for Baraclude and 3 for Epivir HBV. At the last review, a motion for therapeutic alternatives passed unanimously. Significant changes include Rhabdomyolosis was observed in patients taking Tyzeka and a medication guide is to be distributed to patients on this medication.

In response to Dr. Demain, Mr. Campana said this class was not currently on the PDL because it missed the December update, but will be included on the May 18 update.

DR. KILEY MOVED THE DRUGS IN THE CLASS WERE THERAPEUTIC ALTERNATIVES. SECONDED BY DR. BERGESON.

After discussing whether the motion should include a formulation for children 2 to 17 years of age, it was suggested that the medically necessary clause be utilized due to the low number of claims.

THE MOTION PASSED UNANIMOUSLY.

Break from 9:30 a.m. to 9:43 p.m.

19. Re-review of Ophthalmic Mast Cell Stabilizers (Green Category)

Dr. Pritchard gave the Magellen presentation on Ophthalmic Mast Cell Stabilizers. These agents are used for persistent or frequency symptoms of conjunctivitis. Very low or undetectable levels of systemic absorption have been recorded. They are available in solution form. The dosing is one to two drops, twice daily, up to six times a day depending on the drug. In March, there were 2 claims: 100% for Cromolyn Sodium Ophthalmic. At the last review, a motion for class effect passed unanimously.

DR. KILEY MOVED A CLASS EFFECT. SECONDED BY DR. BERGESON.

The committee discussed whether this class was needed. Mr. Campana noted that the P&T Committee could recommend removing a class from the PDL. Dr. Demain felt the committee should consider removing the class at the next review due to the low number of prescriptions and the fact that there were other superior products that assumed the same role.

THE MOTION PASSED UNANIMOUSLY.

20. Re-review of Otic Quinolones (Green Category)

Dr. Pritchard gave the Magellen presentation on Otic Quinolones. Topical treatment by fluoroquinolones is used in cases of otitis externa and chronic otitis media. These agents act by inhibiting DNA gyrase. Drops are generally administered twice daily for 7 days. Cipro HC is non-sterile and should not be used in cases of perforated tympanic membrane. The other products are sterile. Safety and efficacy of otic quinolones is well documented. In March, there were 304 claims: 57% for Ciprodex, 39% for Ofloxacin Optic Drops, and less than 5% for the rest. At the last review, a motion for class effect passed with one opposed.

DR. BERGESON MOVED A CLASS EFFECT. SECONDED BY DR. PAPPENHEIM. THE MOTION PASSED UNANIMOUSLY.

21. Re-review of 2nd & 3rd Generation Quinolones (Green Category)

Dr. Pritchard gave the Magellen presentation on 2nd and 3rd Generation Quinolones. Older quinolones had action against gram-negative organisms and are used mainly to treat UTIs. The newer agents have a broader spectrum of activity, which includes gram negative and gram positive. These agents have good bioavailability. Quinolones are indicated as an alternative for infections caused by human or animal bites and may be used in combination therapy against MRSA skin infections. In March, there were 446 claims: 49% for Levaquin Tablets, 48% for Ciprofloxacin HCL Tablets, and the others were all less than 5%. At the last review, a motion for class effect passed with two opposed. Significant changes include geriatric patients have an increased risk of tendon rupture or other tendon disorders, which can sometimes occur months after use.

Dr. Michaud noted that Ciprofloxacin was the only agent approved for use in patients less than 18 years of age and should be included on the PDL.

DR. MICHAUD MOVED A CLASS EFFECT TO INCLUDE CIPROFLOXACIN. SECONDED BY DR. BERGESON. THE MOTION PASSED UNANIMOUSLY.

22. Re-review of 2nd & 3rd Generation Cephalosporins (Green Category)

Dr. Pritchard gave the Magellen presentation on 2nd and 3rd Generation Cephalosporins. The 2nd generation Cephalosporins are active against gram negative and some gram-positive organisms. The CDC recommends Cephalosporins as first line treatment for gonorrhea infection with 2nd generation agents being just as efficacious as the first line agent Cephalexin, which is a 1st generation. In March, there were 100 claims for the 2nd generation agents: 53% for Cefprozil Suspension, 20% for

Cefuroxime, 19% for Ceftin Tablets, 8% for Ceftin Suspension, and no claims for the rest. At the last review, a motion for class effect, to include at least one good tasting product and exclude Ceclor, passed unanimously. The 3rd generation agents have stronger action against gram negative and resistant strains, as well as against gram-positive bacteria. The adverse drug reaction profiles, drug interactions, warnings, and contraindications are similar. In March, there were 679 claims for the 3rd generation agents: 86% for Cefdinir Suspension, 9% for Cefdinir Capsules, and less than 5% for the rest. At the last review, a motion for class effect passed unanimously.

Dr. Demain noted there would be separate votes for the 2nd generation agents and the 3rd generation agents.

DR. BERGESON MOVED A CLASS EFFECT FOR 2nd GENERATION AGENTS, TO INCLUDE AT LEAST ONE GOOD TASTING PRODUCT AND EXCLUDE CECLOR. SECONDED BY DR. PAPPENHEIM. THE MOTION PASSED WITH ONE OPPOSED.

DR. BERGESON MOVED A CLASS EFFECT FOR 3rd GENERATION AGENTS. SECONDED BY DR. MICHAUD. THE MOTION PASSED UNANIMOUSLY.

23. Re-review of Macrolides (Green Category)

Dr. Pritchard gave the Magellen presentation on Macrolides. Erythromycin was the first macrolide introduced in 1952 with activity against gram-positive cocci and atypical pathogens. Both Azithromycin and Clarithromycin demonstrate better tolerability with more convenient dosing regimens and improved activity against H. influenza. The mechanism of action of the agents was reviewed. Drug interactions, cautions, dosing, etcetera, vary among the agents. In March, there were 1,768 claims: 51% for Azithromycin Tablets, 36% for Azithromycin Suspension, and the rest of the products were less than 10%. At the last review, a motion for therapeutic alternatives, to prefer Azithromycin, passed with one opposed. Significant changes include patients with severe renal impairment may need decreased doses of Clarithromycin.

The committee discussed whether this class was necessary, as all of the agents were available as generics. Mr. Campana said having the agents preferred helped ensure generics were used.

DR. BERGESON MOVED THE DRUGS IN THE CLASS WERE THERAPEUTIC ALTERNATIVES TO INCLUDE AZITHROMYCIN. SECONDED BY DR. MICHAUD. THE MOTION PASSED UNANIMOUSLY.

24. Re-review of Long Acting Beta Agonists (Green Category)

Dr. Pritchard gave the Magellen presentation on Long Acting Beta Agonists. LABAs are used in the treatment and prevention of asthma exercise-induced bronchospasm in COPD. They exhibit activity by increasing the cyclic ANA levels, which relax bronchial smooth muscle. Although the onset of action varies between the drugs, they all last for 12 hours. These LABA agents are for controller purposes and are not meant to replace short-acting inhalers for rescue. In March, there were 8 claims: 62% for Serevent Diskus, and 37% for Foradil Aerolizer. The long-acting product, Brovana, had 2 claims. At the last review, a motion for therapeutic alternatives, to include Salmeterol and Formoterol, passed with four opposed.

Dr. Liljegren asked if an agent had to be preferred to include the combination products. Mr. Campana said there was an advantage to including a drug on the preferred list. These drugs also have step-edits unless there is proof the drug is being used for COPD.

Dr. Demain noted that these drugs could not be used by themselves for children with asthma. There was also a study looking at patients with COPD and inhaled steroids showing a significant increase in the development of pneumonia. Therefore, in COPD patients, it is trending even more toward using the long-acting bronchodilators independent of an inhaled steroid.

DR. LILJEGREN MOVED A CLASS EFFECT TO INCLUDE ONE HAND-HELD DEVICE. SECONDED BY DR. BERGESON. THE MOTION PASSED UNANIMOUSLY.

25. Re-review of Short Acting Beta Agonists (Green Category)

Dr. Pritchard gave the Magellen presentation on Short Acting Beta Agonists. Agents in this class are available in typical inhaler form or nebulizer solution form. These drugs are reserved for acute exacerbation of asthma symptoms as they have a quick onset of action. They are not to be used as controller medications. There are no contraindications for these drugs. All can be dosed every four to six hours as needed with duration of action between two to eight hours depending on product. In March, there were 2,138 claims for the inhaler form and 686 for the nebulizer form. For the inhaler form: 38% for ProAir, 30% for Ventolin HFA, 25% for Proventil HFA, and the other products were less than 10%. For the nebulizer form: 88% for Albuterol Sulfate and less than 10% for the rest. At the last review, a motion for class effect, to include Albuterol HFA preparation, passed unanimously.

DR. LILJEGREN MOVED A CLASS EFFECT, TO INCLUDE ONE ALBUTEROL HFA AND ONE NEBULIZED PREPARATION. SECONDED BY DR. BERGESON. THE MOTION PASSED UNANIMOUSLY.

26. Re-review of COPD Inhalant Drugs (Green Category)

Dr. Pritchard gave the Magellen presentation on COPD Inhalant Drugs. Bronchodilators are central to the management of COPD symptoms. A short acting agent, used as needed, is recommended for mild disease. For moderate to severe disease, scheduled use of one or more bronchodilators is recommended. The anticholinergic agents exert activity by blocking cholinergic neurotransmission, thereby causing bronchodilator. The most common adverse event is dry mouth, which resolves with continued use. In March, there were 426 claims: 42% for Combivent, 35% for Spiriva, 12% for Ipratropium-Albuterol, and the other products were less than 5% each. At the last review, a motion for class effect, to include one long acting and one combination product, passed unanimously.

Dr. Demain noted that although not FDA approved, there was a study looking at the use of Tiotropium or Spiriva as an add-on therapy with inhaled steroids for asthma has shown it to be as effective as long-acting bronchodilators.

DR. BERGESON MOVED A CLASS EFFECT TO INCLUDE ONE LONG-ACTING AND ONE COMBINATION PRODUCT. SECONDED BY DR. CARLSON. THE MOTION PASSED UNANIMOUSLY.

27. Re-review of Ophthalmic Immunomodulators (Green Category)

Dr. Pritchard gave the Magellen review of Ophthalmic Immunomodulators. The only indication for this class is to treat dry eye disease. The exact mechanism of action is unknown at this time. Systemic absorption is almost non-detectible. The sensation of burning was the most commonly reported side effect. Restatis is dosed twice daily. In March, there were 22 claims. At the last review, a motion for class effect passed unanimously.

DR. KILEY MOVED A CLASS EFFECT. SECONDED BY DR. BERGESON. THE MOTION PASSED UNANIMOUSLY.

28. Re-review of Hepatitis C Agents (Green Category)

Dr. Pritchard gave the Magellen review on Hepatitis C Agents. Hepatitis C is the most common blood-borne infection in the U.S. Transmission occurs through contact with infected blood. The pegylated products inhibit virus replication inside the infected cells via a complex set of events. In March, there were 6 claims: 33% for Peg-Intron, 33% for Pegasys, 17% for Peg-Intron Redipen and 17% for Pegaysis Convenience Pack. Ribavirins are used in combination with the pegylated interferons. In March, there were 6 claims: 5 for Ribavirin and 1 for Rebetol Solution. At the last review, a motion for class effect passed unanimously. Didanacine and Ribavirin therapy is contraindicated. Ribavirin is genotoxic and mutagenic and should be considered a potential carcinogen. All drugs in this class require a medication guide be given to the patient.

DR. CARLSON MOVED THE DRUGS IN THE CLASS WERE THERAPEUTIC ALTERNATIVES, TO INCLUDE ONE INTERFERON AND ONE RIBAVIRIN PRODUCT ON THE PDL. SECONDED BY DR. KILEY. THE MOTION PASSED UNANIMOUSLY.

29. Re-review of Anti-Fungal - Onychomycosis (Green Category)

Dr. Pritchard gave the Magellen review on Anti-Fungal - Onychomycosis. Dermatifites, yeast, and molds are causative pathogens of infections of the nail bed, occurring more often in toenails versus fingernails. It is generally hard to treat and the infections tend to occur more frequently in the elderly. In March, there were 61 claims: 79% for Terbinafine, 11% for Griseofulvin Oral Suspension, and less than 5% for the rest. At the last review, a motion for class effect, to include at least one other agent in addition to Griseofulvin, passed unanimously. Griseofulvin can have adverse effects on fetuses. Males should wait at least six months after cessation of therapy to father a child. Lupus-like syndromes have been reported with this drug. Photosensitivity and severe skin reactions may occur. Elevated LFTs and jaundice have also been reported. For Terbinafine, taste disturbances and depressive symptoms have been reported.

Dr. Liljegren lobbied not to include Griseofulvin on the PDL, because it is an inferior drug. Dr. Demain said Griseofulvin was used for children, especially those with tinea capitis. Dr. Liljegren suggesting placing an age restriction on the Griseofulvin.

DR. LILJEGREN MOVED THE DRUGS IN THE CLASS WERE THERAPEUTIC ALTERNATIVES, WITH GRISEOFULVIN INCLUDED ON THE PDL FOR PATIENTS 17

YEARS OF AGE AND UNDER. SECONDED BY DR. BERGESON. THE MOTION PASSED UNANIMOUSLY.

30. Re-review of Topical Antibiotics (Green Category)

Dr. Pritchard gave the Magellen review on Topical Antibiotics. Mupirocin irreversibly and specifically binds to a bacterial enzyme resulting in inhibition of protein biosynthesis. Altabax is the first in a new class of antibacterial, the pleuromutilins, which inhibit normal bacterial protein biosynthesis by binding at the unique site (L3) on the ribosomal 50S subunit. The mechanism of action of the other agents was reviewed. The cream and ointment formulations are not interchangeable. In March, there were 451 claims: 81% for Mupirocin, 14% for Bactroban Cream, and less than 5% for the rest. At the last review, a motion for class effect passed unanimously. Centany, the Mupirocin ointment, is not indicated for nasal use.

In response to Dr. Demain, Dr. Hope said the Bactroban cream and ointment came in different package sizes. If the prescription is written for Bactroban, quantity 30 grams, then the cream is dispensed by default since the ointment is a 22-gram product. The DUR Committee will be looking at placing that on a step-edit or prior authorization.

DR. BERGESON MOVED A CLASS EFFECT. SECONDED BY DR. CARLSON. THE MOTION PASSED WITH THREE OPPOSED.

Dr. Michaud and Dr. Liljegren said they opposed since the motion was is for class effect. Mupirocin is the only agent that is effective against MRSA and should have been preferred. The committee discussed whether a second motion was necessary. It was noted that Mupirocin has been generic for some time and would probably be included on the PDL. Mr. Campana noted that since Mupirocin was a preferred agent in the past, it was likely it would remain on the PDL. After further discussion, the committee decided to amend the motion.

DR. BERGESON MOVED TO RECONSIDER THE PREVIOUS MOTION AND AMEND IT TO STATE THAT THE DRUGS IN THE CLASS WERE THERAPEUTIC ALTERNATIVES, TO INCLUDE MUPIROCIN ON THE PDL. SECONDED BY DR. CARLSON. THE MOTION PASSED UNANIMOUSLY.

31. Re-review of Topical Antifungals (Green Category)

Dr. Pritchard gave the Magellen review on Topical Antifungals. Ciclopirox is active against many types of fungi, including dermatifites (ph) and yeast. The mechanism of action is through inhibition of metal dependent enzymes needed for the organism to degrade the peroxides. It should not be used in patients with a history of seizures or immunosuppression. The only agent being considered is Ciclopirox. In March, there were 8 claims. The previous discussion and motion was not available.

Dr. Demain said most of the topical antifungals were available over-the-counter and work well. The committee discussed whether an over-the-counter product could be included on the PDL. Mr. Campana said a regulation change would be necessary to add an over-the-counter product on the PDL, which would take about a year to accomplish. Dr. Pappenheim felt the committee should pursue the ability to add over-the-counter medications on the PDL in the future. Dr. Hope noted that any over-the-

counter products that are brought into coverage, you also have to cover them for the Medicare D population that is covered under Medicaid, which would potentially expand the number of claims received.

DR. BERGESON MOVED A CLASS EFFECT. SECONDED BY DR. KILEY. THE MOTION PASSED UNANIMOUSLY.

32. Review Minutes from January 2011 Meeting

Mr. Campana reviewed the corrections to January 2011 meeting minutes.

DR. BERGESON MOVED TO APPROVE THE JANUARY 2011 MEETING MINUTES AS CORRECTED. SECONDED BY DR. KILEY. THE MOTION PASSED UNANIMOUSLY WITH DR. LILJEGREN ABSTAINING.

33. Comments from Committee Members or Chair

Mr. Campana said the next meetings would be September 16, 2011; November 18, 2011; January 20, 2012; and April 20, 2012. All of the committee members were thanked for their work on the P&T Committee. The program has been very successful since its inception in 2003 and has saved the state millions of dollars. The PDL has been available online since 2004. Statins and PPIs will be removed from the PDL and placed under step-edits to ensure generics are utilized first. An E-Prescribing module will be available early this summer. It will provide prescribers with a picture of the recipient's medical utilization and pharmaceutical history. A new pharmacy payment methodology will be available by the end of June.

34. Adjourn

DR. KILEY MOVED TO ADJOURN THE MEETING. SECONDED BY DR. BERGESON. THE MOTION PASSED UNANIMOUSLY.

The meeting adjourned at 10:45 a.m.